

# The Goldilocks Principle of Vaccines Storage and Handling

# *The Goldilocks Principal*

Not Too *HOT*!!

Not Too *COLD*!!

*Temps must be JUST RIGHT!*

*2 c to 8 c and -15 c to -50 c*

*Or Bad Things Happen....*

# Why Me?

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General pediatrics – Coastal Children's Clinic  
New Bern, Havelock & Maysville

In practice since 1985

Tremendous fan of the NC Immunization Branch

Active in the NC Pediatric Society as Co-Chair of  
our Pediatric Council along with Dr. Diasio

Member of AAP's National Committee, COPAM  
(Committee On Practice and Ambulatory Medicine)

COPAM exists in the AAP to give an analysis of how new policies will affect office-based pediatricians.

We were tasked with responding last May to the Office Of the Inspector General's report on the handling and storage of VFC vaccine in offices and clinics. It was not pretty.

# OIG Report Findings

The report pointed out that there was a tremendous need for better awareness of proper storage and handling of vaccines by Pediatricians.

Vaccination is arguably the single most important thing we do as Pediatricians – we need to be the best in the country at storing, handling and delivering fully potent vaccines! I admitted to knowing about refrigeration, so .... I was assigned the task of increasing the awareness and skills of our members in storage and handling.

# OIG Report Findings

- Studied 45 VFC providers from the 5 largest VFC Grantees (NC is the 6<sup>th</sup> largest VFC Grantee...) for a 2 week period
- Measured storage unit temperatures using a TempTale Air Data Logger designed for shipping vaccine coolers
- Found 76% of the 45 practices were exposed to inappropriate temps for at least 5 cumulative hours
- No measure of actual damage to vaccine was done – only compliance with CDC recommended storage rules

If you want to learn a lot, go  
somewhere without much!



# But Why The Interest in Refrigeration?



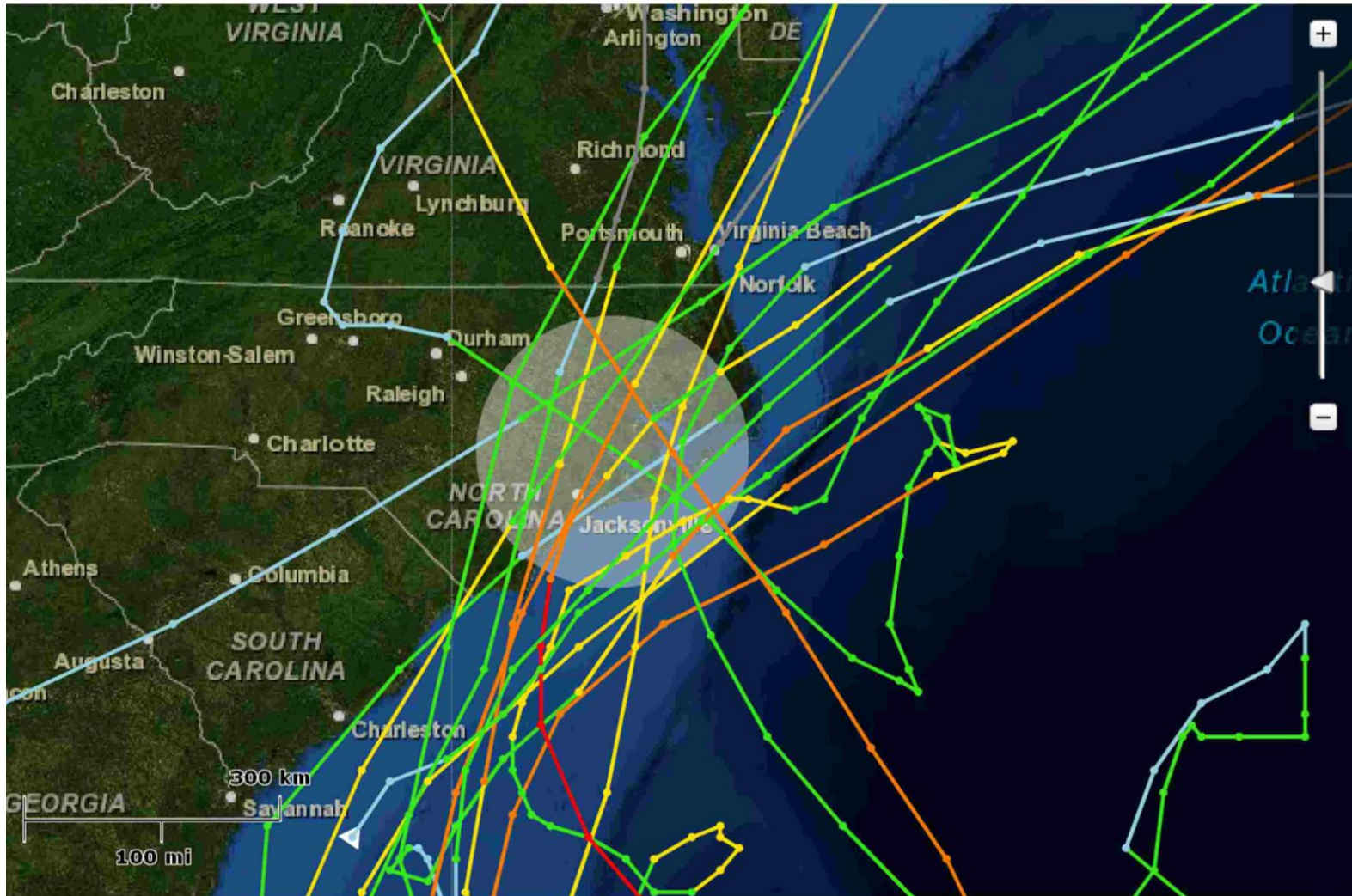


# No Electricity, No Repairmen....

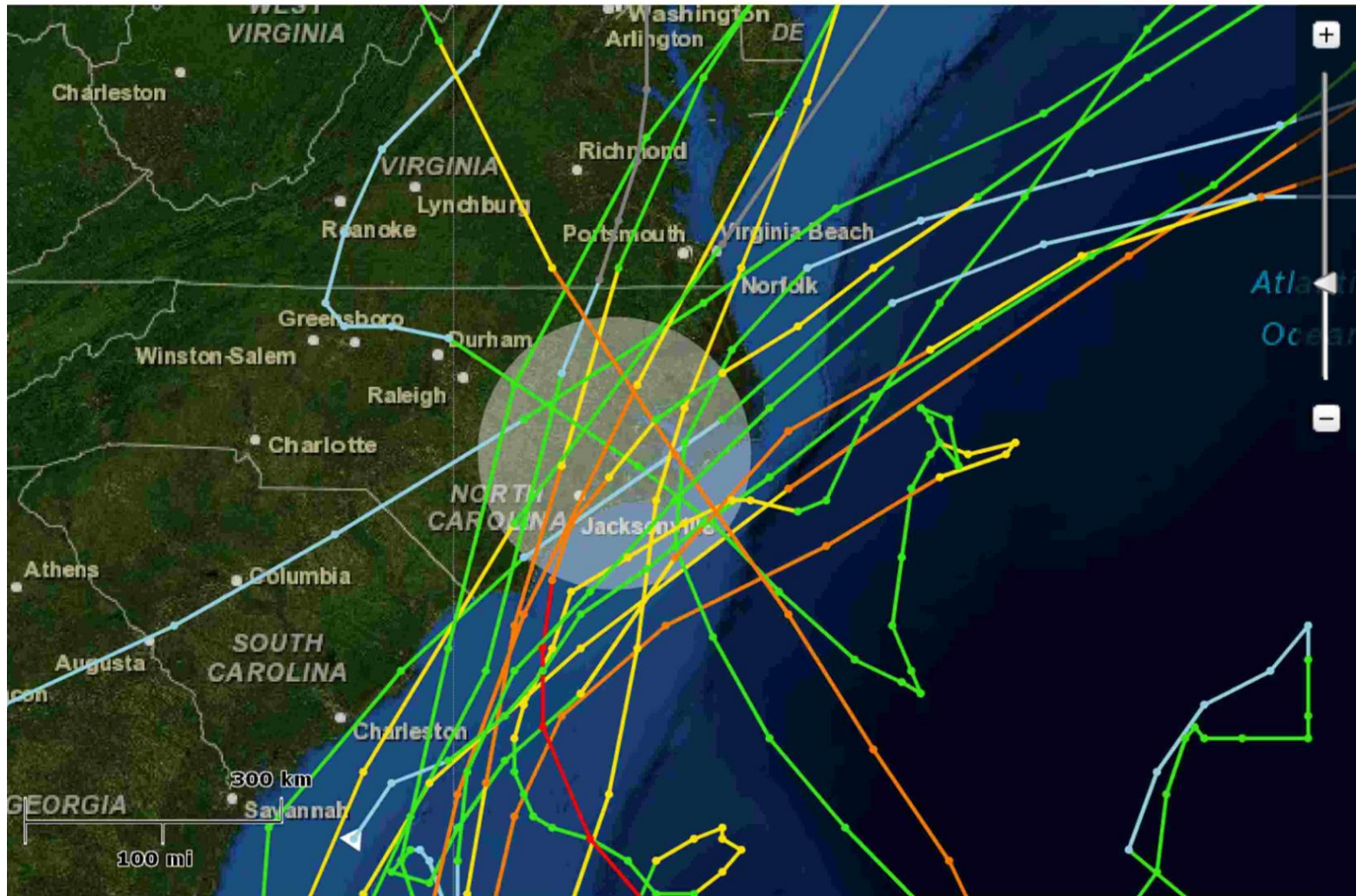
I learned about refrigeration from a 1950's Servel Propane ammonia absorption refrigerator – as a child I was determined to learn how lighting a blow torch at the bottom of the refrigerator made it cold – and I learned!

I also learned about Generators, Coolers, Ice, Electrical, all sorts of skills that are useful here!

# Learned about power outages....



# And how to emergently transport vaccine



# I started off by losing a bet....

Until I read the OIG report, I had never cared about vaccine refrigerators. They were utilitarian. Filled a need. A refrigerator is a refrigerator is a refrigerator. In fact, the only pediatrician I knew who *had* medical grade refrigerators was my Co-Chair of the NC Peds Council, Christoph Diasio. In talking him into helping me do the education part, I made a bet – I bet I could get the right thermometers & data loggers, fill my fridges with water bottles and prove that mine were just as good as his big-city uptown shiny medical ones...



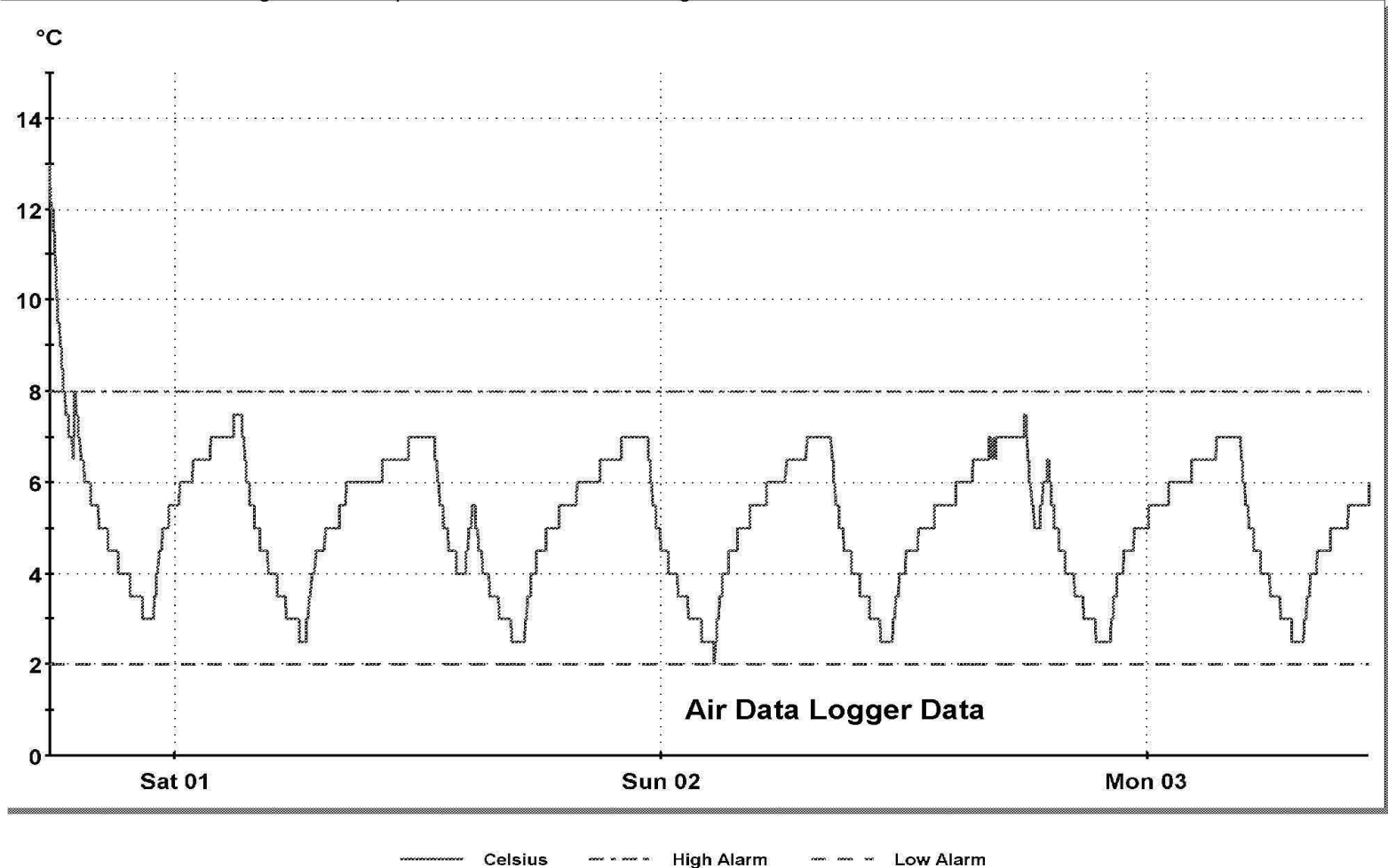
# I started off by losing a bet....

So I spent 3 months last summer tweaking and re-tweaking our refrigerators. I even had one to die a slow death on a Friday afternoon and spent hours looking for a replacement – learning that medical refrigerators take weeks to receive and there is not much to pick from locally. The last straw was when I retested a tweaked refrigerator a few weeks after making it perfect, and I got a graph that looked like...

Temp curve very dependent on fridge loading. I lost the bet!

NBCTs083112

Bulk Combo Refrigerator E Top Shelf Water bottles along the rear and around the vents



From:- 31 August 2012 17:51:41    To:- 03 September 2012 10:57:41

# Not Too Cold - Not Too Hot

## The talk will cover....

### Part 1

- Basic Science of Refrigerators
- Basic Science of Water & Ice
- Safer Way Not to Transport – Shelter In Place

### Part 2

- Safer Way to Transport if you must
- How to Verify your Thermometer

I will be cramming 3 hours into 1, so hold on and hopefully the handouts will fill in the gaps!

# Basic Science of Refrigerators

Compressing gas heats it up – SCUBA tanks get quite warm when filled

Expanding gas gets cold – whether water on your skin is expanding to water vapor and chills you or discharging a CO<sub>2</sub> fire extinguisher creates dry ice – the process is the same:

Expansion = Cold      Compression = Hot



# Basic Science of Refrigerators

Refrigerators use a compressor to pressurize a gas, then routes the high pressure gas through small exterior coils to dump excess heat. Then the coils enter the refrigerator through an expansion valve at the start of the “evaporator coils”. The size of the orifice helps to determine how cold the coils will be – refrigerator vs. freezer. The gas condenses in the large evaporator pipes, falls down and is re-pumped through the compressor to start over on the high pressure side.

# Types of Refrigerators/Freezers

## Combo Domestic Refrigerator –

The classic home refrigerator we all grew up with that has a freezer on top and a refrigerator on bottom. There is only one thermostat that controls the compressor and it is in the refrigerator portion. The freezer “temp control” if present merely controls a small baffle in the freezer that allows more or less super cold (-20c) air to fall into the refrigerator. To change the temp in either compartment, you need to change *both* controls. These are terrible for vaccines due to freeze risk and *should be replaced ASAP.*

# Types of Refrigerators/Freezers

Stand Alone Refrigerators / Freezerless  
Refrigerators / Refrigerator-Only  
Refrigerator (all are the same)

These are much safer for vaccine – the evaporator coil is optimized for refrigerator temps – not freezer temps as is the case with combo refrigerators. You should still be careful that the vaccine can not come directly in contact with the “cold plate” cooling surface which is often along the back wall. These are relatively inexpensive - \$700 to \$1000 – and “basic”.

# Types of Refrigerators/Freezers

## Dual Refrigerators / Twin Cooling

“Dual” refrigerators usually refers to a separate freezer compartment and a separate refrigerator compartment. Each has its own evaporator coil and thermostat optimized for that compartment. Generally seen in some medical units. Samsung is the only company making a domestic (home) version (“Twin Cooling”) with 2 separate evaporator coils. It is easily and quickly available locally but layout not optimal....

# Types of Refrigerators/Freezers

Medical / Pharmacy / Purpose Built  
/Laboratory / Blood Bank Refrigerator

These are the most appropriate for vaccine storage. The best have electronic thermostats with digital displays set at the factory – no need to adjust, just plug in. They have internal circulating fans to lessen hot and cold spots. They have wire shelves to enhance air flow. Can come with glass doors to help with inventory and retrieving vaccine. Quick to recover temp after door opening. Door alarms available and generally have probe ports built in.

# Types of Refrigerators/Freezers

## Freezers –Auto-Cyclic Defrost & Frost Free; Manual Defrost

Frost-free freezers are usually part of combo units which should not store frozen vaccine per CDC. They are somewhat problematic as a stand-alone for vaccines because they warm the evaporator coils to melt frost up to 4 times a day generating a temp up to minus 10C for 10 to 20 minutes. Some high end medical freezers can defrost without warming the compartment. Manual defrost units never thaw their coils and ice can build up requiring removal of vaccine while being defrosted.

# Design Matters

The vast majority of all vaccine “accidents” could be avoided with Medical Grade refrigerators.

Vaccines are much safer if their compartment is not chilled by a freezer as in disallowed dorm refrigerators. I believe combo domestic refrigerators need to *all be replaced*. The top shelf is not safe, nor is the door & possibly vegetable bins. They are not designed to be responsible for \$20,000 or more of vaccine!

**DESIGN MATTERS!**

# Ice and Water – Basic Science

Magical thermal properties of H<sub>2</sub>O:

Specific Heat: The heat required to change a unit mass of something by 1 degree C

Latent Heat: The heat released or absorbed during a phase change (water>ice; ice>water) without any change in temperature



# Specific Heat / Latent Heat

The Specific Heat of Water = Twice the SH of Ice  
But the Latent Heat of water/ice is 80 times the energy required to warm/cool water 1 degree!

To warm 1 kg ice from -16C to ice @ 0C (16 degrees) requires the same amount of energy as 1 kg water going from water at 1C to 9C.  
Ice does not have much “cold” capacity!

But the Latent Heat of water/ice = 80 times the heat required to warm water 1 degree!

This means that 1 kg of ice at 0c melting completely to 1 kg of water at 0c (no change in temp in melting) has the same “heat absorption” as 80 kg of water warming 1c!

During a power outage, placing a 10 lb bag of “wet ice” in the bottom of your fridge has the same cooling capacity to stay below 9c as having 200 pounds of 5c water in the bottom when the power died!

*Melting Ice is the key!*

So imagine peacefully sleeping at home after a long day and the phone rings 1 am –

Instead of the usual medical question, a computerized voice identifies itself as your refrigerator and it needs HELP!

What are you going to do?

So what do you do at 1am??  
You go to your office to protect the  
vaccine and decide to...

**Do the Shelter Shuffle!**

Or-

How to put your vaccine in a safe  
place without really going  
**ANYWHERE!**

# Most Vaccine Threatening Events

Are simply loss of refrigeration either through power outages or equipment failure or even a door being left open.

During such events where the integrity of the building is not at risk, it makes more sense to safely store the vaccine on site than to move to a hospital or other facility and risk the pitfalls inherent with moving!

# Shelter Equipment Needed

- Coolers of sufficient size and number to store all vaccine including sufficient room for coolant
- Sufficient frozen water bottles to provide the necessary coolant for refrigerated vaccine
- Frozen gel packs and smaller separate cooler with thermometer to transport frozen vaccine off site for safe storage
- Wireless thermometers for all coolers (optional)

# Shelter Equipment Needed

- Certified thermometer(s) and or data logger(s) to remain with the vaccine in the cooler(s)
- Trash bags to help segregate the public and private vaccine
- A good “camping lantern” light to help pack the vaccine in the dark during power outages

# The Shelter Shuffle-

You need to decide quickly – solid door refrigerators have 3 hrs, glass doors less.

Using coolers like you were going to transport (discussed later):

Pre-chill your coolers with frozen coolant while deciding the next step. Condition many (~10-20 per large cooler) frozen water bottles. Remove the freezer packs, place the refrigerated vaccine in trash bags (being careful to segregate the VFC from the Private stock) and place in coolers along with the CFWBs. Put in a wireless thermometer if available and tape the lid shut.

## Go Home!



# The Shelter Shuffle-

But I wanted an even easier method – to see if a modern refrigerator could function like an old fashioned Ice Box –

How long could I keep a solid door refrigerator that has been unplugged at a temperature of 2c to 8c ?

And if the only source of ice died when the refrigerator died?

# The Shelter Shuffle-

- I filled an old domestic combo refrigerator freezer compartment with 62 half liter water bottles and froze them solid.
- I put a data logger and a wireless thermometer on the middle shelf and I pulled the power plug.... I wanted to simulate a power outage and use only what was available when the power turned off.

# The Shelter Shuffle-

I immediately took 24 of the frozen water bottles out of the freezer and onto the top shelf in the refrigerator (Never have vaccine on the top shelf of a combo!)

When the temp reached 8c, I removed those 24 and put in 30 more leaving 8 un-used in the freezer compartment.

Any guess as to how long the “Hang Time” of that ice box before going above 8c?

# Shelter In Place – No Shuffling

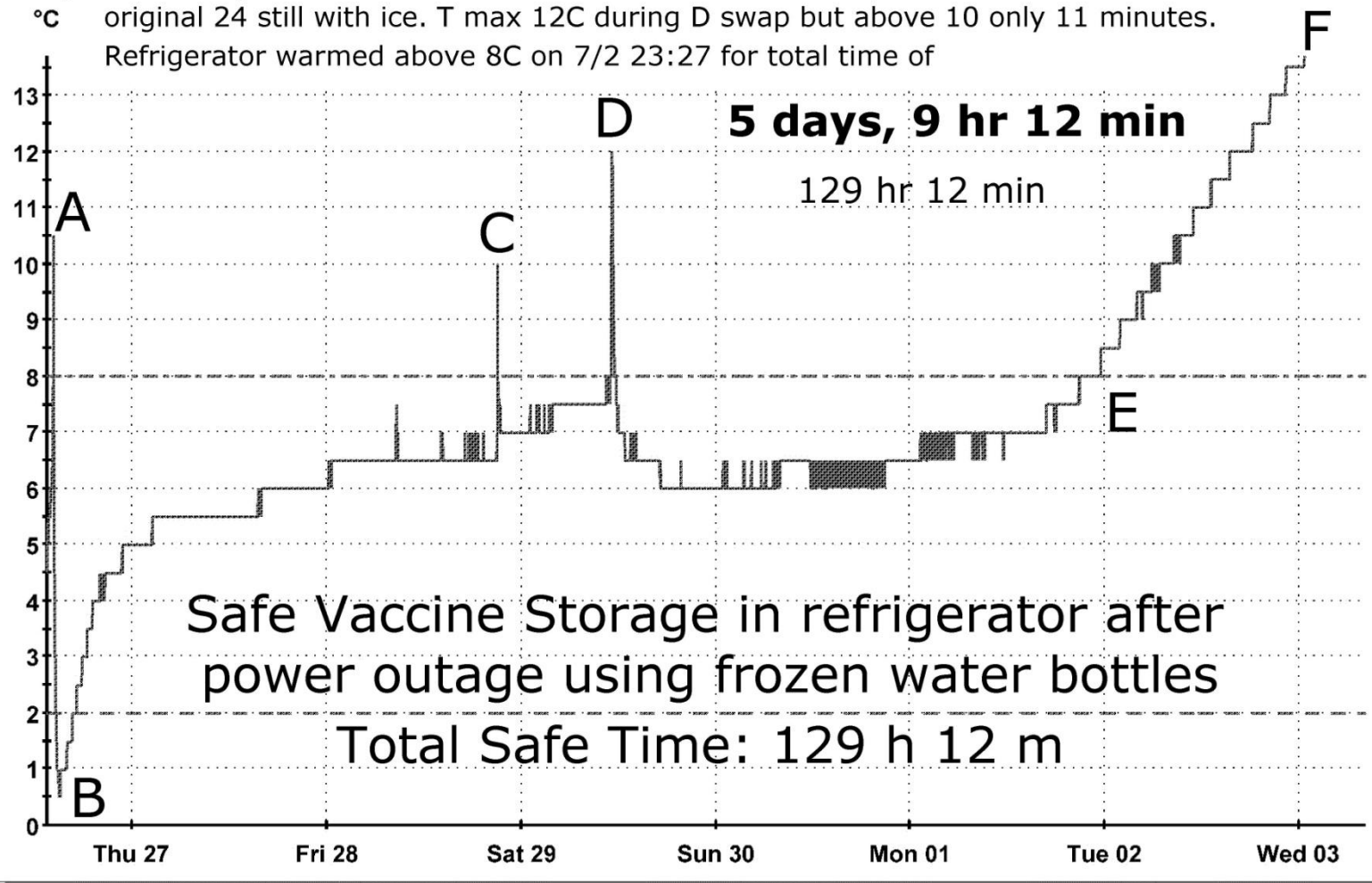
## **129 hours!**

5 days 9 hours after a power outage using only the frozen water bottles present at the time the power was stopped! Plenty of time to figure out what to do next....

Test of Power Off of Combo Refrigerator Pre Stocked with 62 half liter water bottles frozen in freezer 6/26 @ 12:00. 24 were moved to top shelf A at 14:15. Coldest point B = 0.5C. Door open C for check.

Door opened at D 2/29 11:15 33h and 24 bottles removed and replaced with 30 from freezer. 14 of original 24 still with ice. T max 12C during D swap but above 10 only 11 minutes.

Refrigerator warmed above 8C on 7/2 23:27 for total time of



----- Celsius    - - - - - High Alarm    . . . . . Low Alarm

From:- 26 June 2013 13:30:46    To:- 03 July 2013 08:15:46

I also tried a 72 quart fishing cooler



These are Conditioned Frozen Water  
Bottles CFWB – discussed later



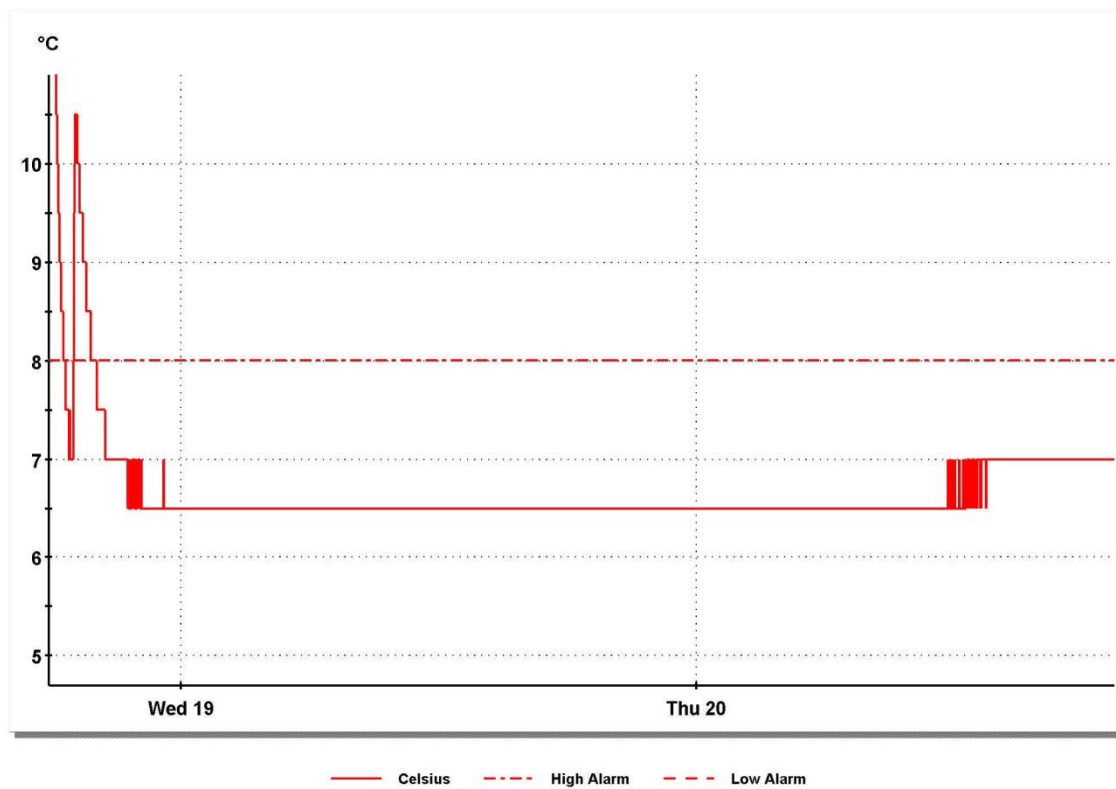






# 48 hours easily!

72quartTest



From:- 18 June 2013 17:52:43 To:- 20 June 2013 19:26:43

# Shelter Shuffle = Shelter In Place

- Often a safer alternative than transporting vaccine in emergency situations
- Good idea to consider when an unexpected power outage occurs and duration expected is unknown. Refrigerators are generally above 8c in 3 hrs or less.
- Probably not appropriate for frozen vaccine – but much easier to find a working freezer for such a small volume. Don't forget your thermometers!

# Transportation of Vaccine

If you have to go, go in  
style!

# Why Transport?

- Multiple offices may need to “re-balance” stock
- Fridge failure without a suitable backup on site
- A severe weather event may be approaching with power outage anticipated

(Remember, opened multidose vials are not allowed to be transported and used in a different facility as per FDA regulations)

# Types of Transport

## Duration of transport

- Short office-to-office lasting 2 hours or less
- Longer duration of up to 48 hours
- Open ended or indeterminate period of “Sheltering In Place”

## Product being transported

- Transport of *Refrigerated* vaccine
- Transport of *Frozen* (Varivax) vaccine

# Types of Transport Failure

- Temperature briefly Too Cold – disastrous freezing with total loss of vaccine
- Temperature mildly Too Warm – usually recoverable after calling manufacturers or VFC manager
- Total Loss of vaccine (wreck, theft, negligence)

Refrigerated  
(not Freezer)  
Transport

# Temperature Too Cold

- Absolutely the most common cause of rapid vaccine loss
- Can happen in minutes
- Often undetectable as it happens!
- Often undetected after it happens!



# Golden Rule of Refrigerated Transport

*“If Nothing in the Vaccine Cooler is Below Freezing, You Cannot Freeze Vaccine!”*

What commonly is used to chill vaccine that can be below 0c?

Almost everything!

- Frozen Gel Packs
- Hard frozen Water Bottles
- Unmonitored or poorly designed portable electric 12v transport coolers

# What cannot be below Zero c?

There are only two real choices:

- Refrigerated gel packs which do not hold cold any longer than cold water packs
- Conditioned Frozen Water Bottles (CFWB) take 60-120 seconds to condition and are *Excellent* at maintaining non-freezing cold!

# Gel Packs

The Good, The Bad, and the Mostly Ugly Gel Pack:

## Complicated CDC Recommendations:

Coolant packs that are frozen must be “conditioned” by leaving them at room temperature for 1 to 2 hours until the edges have defrosted and the packs look like they’ve been “sweating.” Frozen coolant packs that are not “conditioned” can & will freeze vaccine.

# Gel Packs

Are not all created equally –

- They can have varying “freeze points” – most are at about -4C, but can be colder or warmer
- The freeze point or “phase change” temp determines how cold the pack will stay for the majority of its cold life. If that is -4C, vaccines are at risk as long as it is frozen. And if it is not frozen, it will not stay cold!
- No one wants to wait 1 or 2 hours before packing a cooler in an emergency!

# Best Practice

Conditioned Frozen Water Bottles (CFWB) are the perfect transport coolant!

- Easily available - \$4 or less for 24 half liter bottles
- Properties of water are absolutely predictable
- Conditioning a frozen water bottle takes only 1 or 2 minutes and you have an absolute visual confirmation when it is conditioned –  
Visible Liquid Water Means **CONDITIONED!**

# How Does a Frozen Water Bottle Become a CFWB?

- Hard freeze a water bottle and place under running tap water or a sink with water for 60-120 seconds
- Once a small amount of liquid water is visible in the bottle, it is “conditioned” – remove & use!

*Remember: Water + Ice defines Zero C – the bottle absolutely cannot be below zero with visible liquid water in the bottle!*

Free Water in a CFWB = 0C!





# Coolers

Short Trips – Almost anything will work

- Avoid Igloo Playmate style – sliding top – the top is not insulated

Longer trips – Insulated hard shell coolers with tightly fitting tops and easy to carry

Longest Trips – Shelter In Place – Use the very thick Styrofoam coolers in which the vaccines are shipped or good quality “fishing” coolers

Remember to protect from freezing in the winter!

# Packing CFWB Coolers

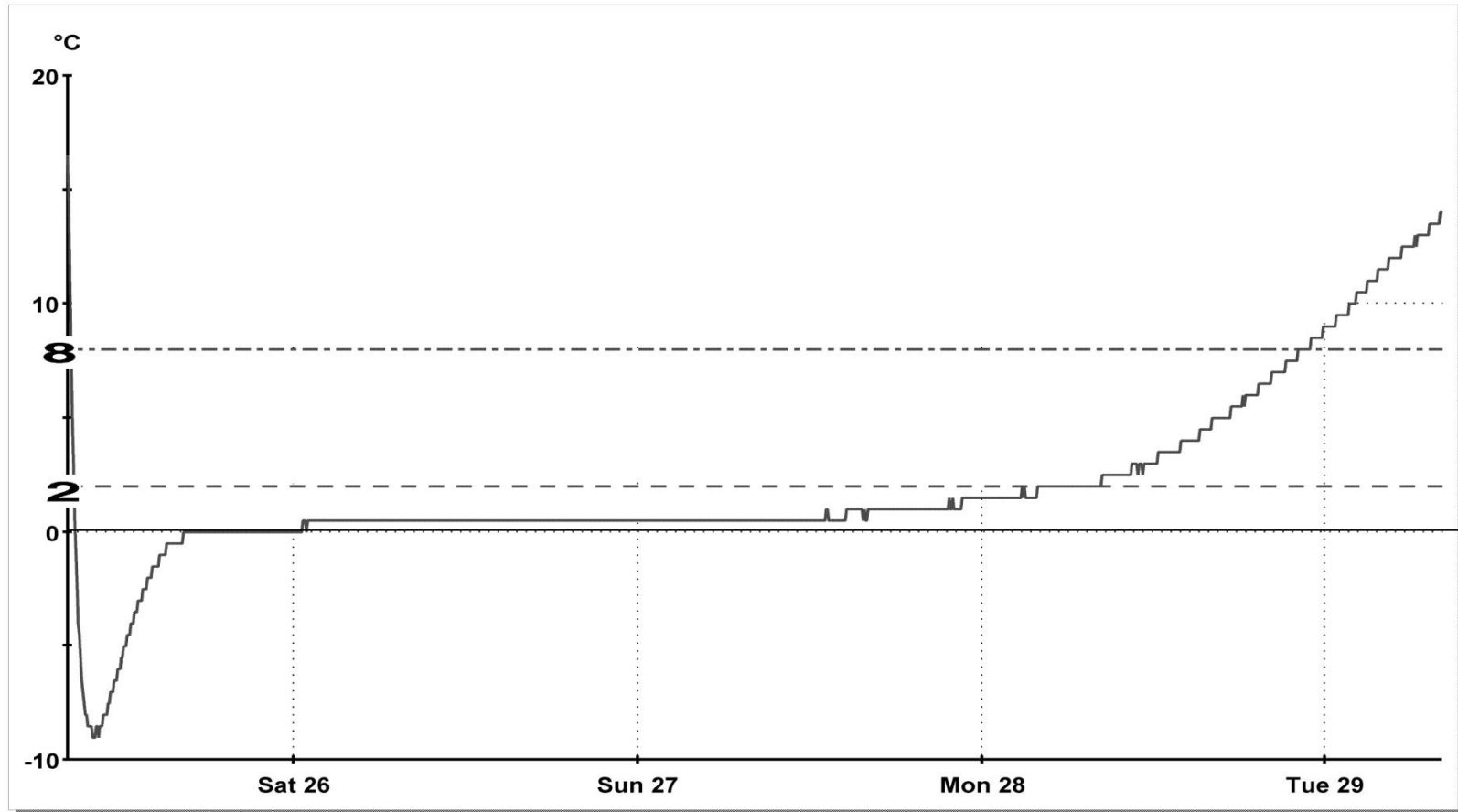
- All coolers work best if pre-chilled
- When using CFWB, it is not important to use bubble wrap to protect the vaccine from being too cold! CFWB cannot be too cold!
- Do use some paper towels or other paper to protect from condensation moisture
- Put a layer on the bottom and even more on the top – the top layer is the most important and should equal or be more than bottom layer

# Test Cooler for CFWB



# Frozen Gel Packs = Frozen Vaccine

6.5 lbs Hard-frozen Gel Freezer Packs in Small PolyStyrene Cooler Demonstrating Freeze Risk

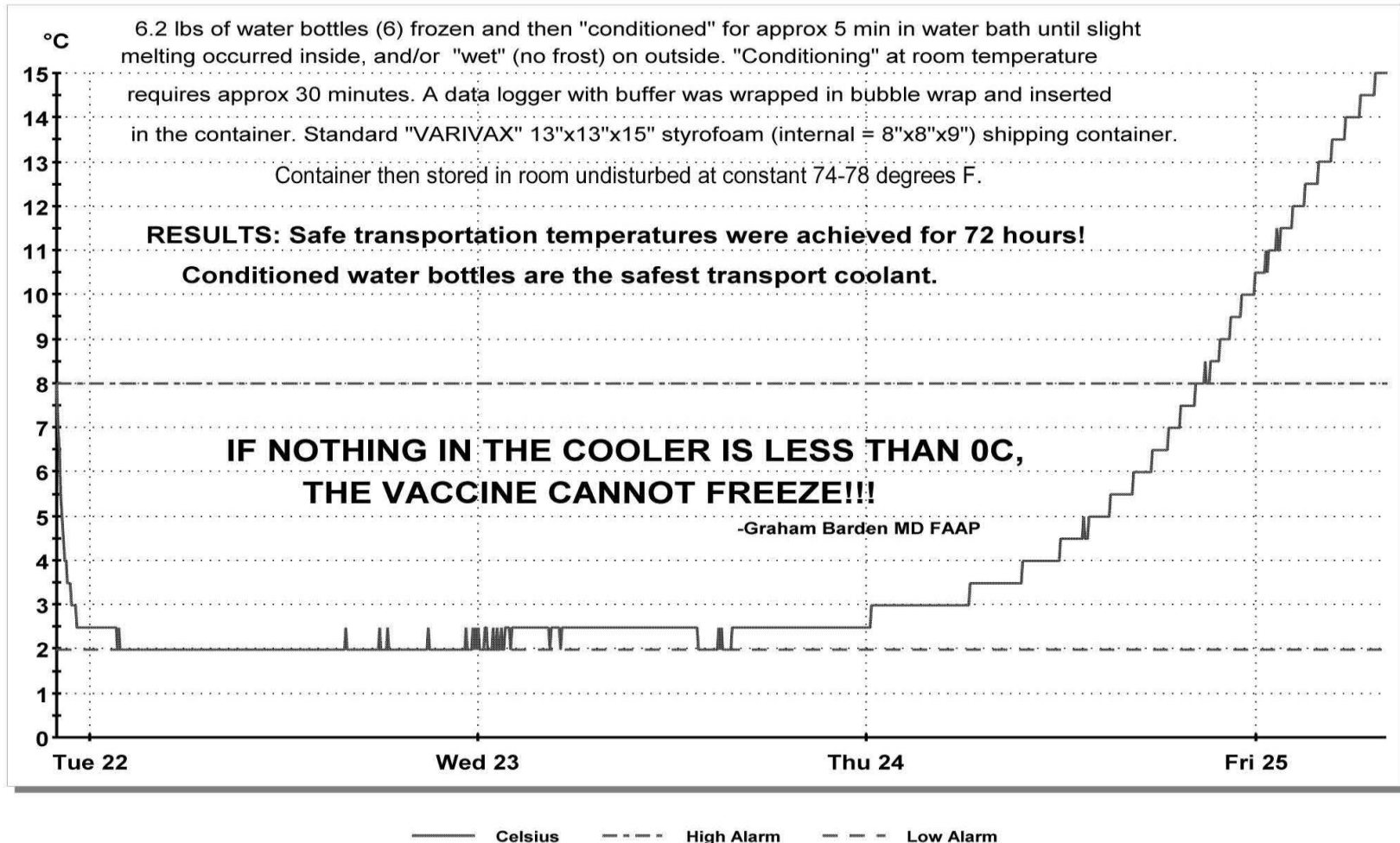


Approx 16 hr  
Freeze Risk

From:- 25 January 2013 08:12:43 To:- 29 January 2013 08:07:43

# CFWB As Coolant

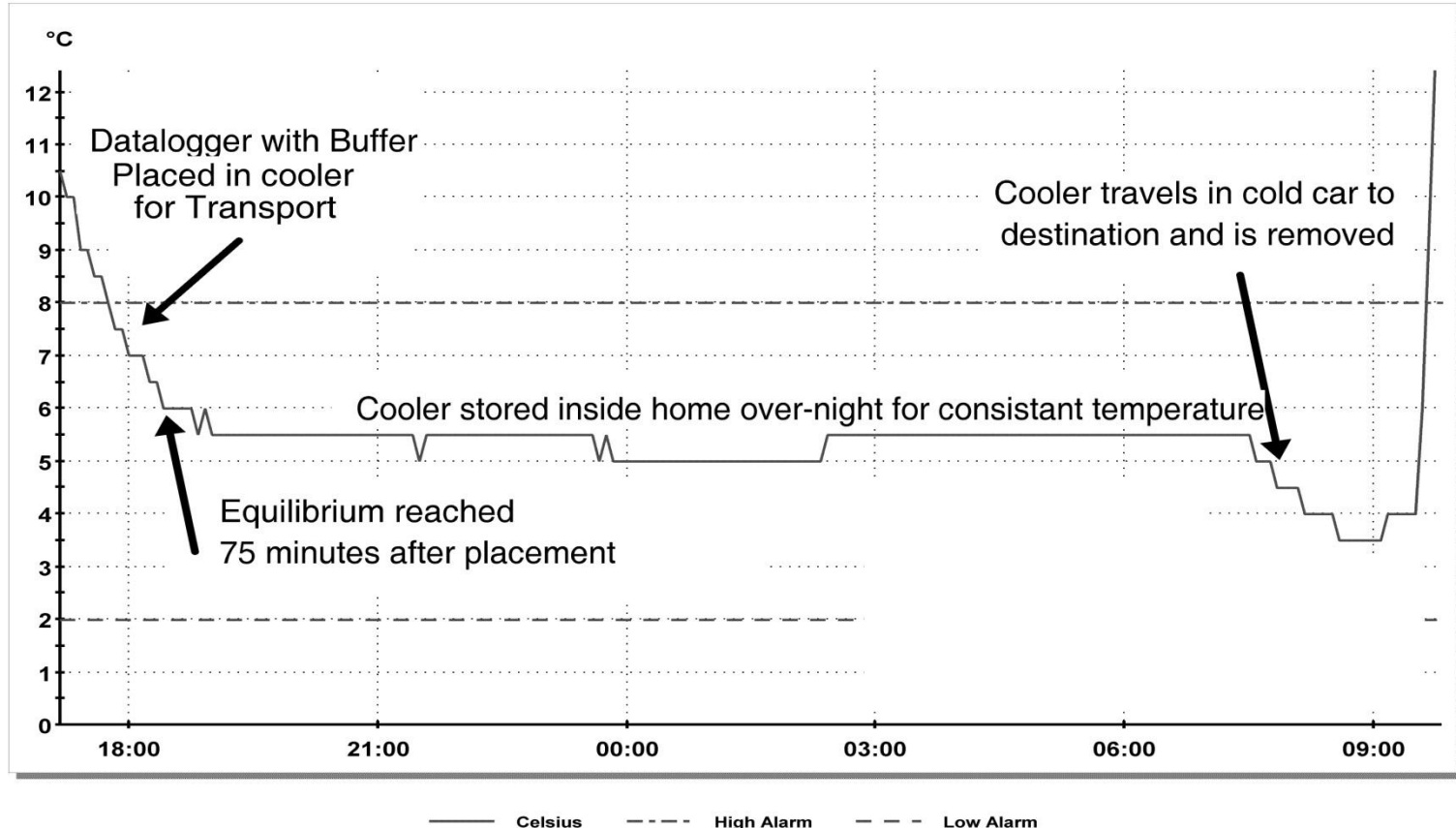
## Conditioned Frozen Water Bottles as Colant For Vaccine Transport



From:- 21 January 2013 21:59:47 To:- 25 January 2013 08:04:47

# Overnight Transport

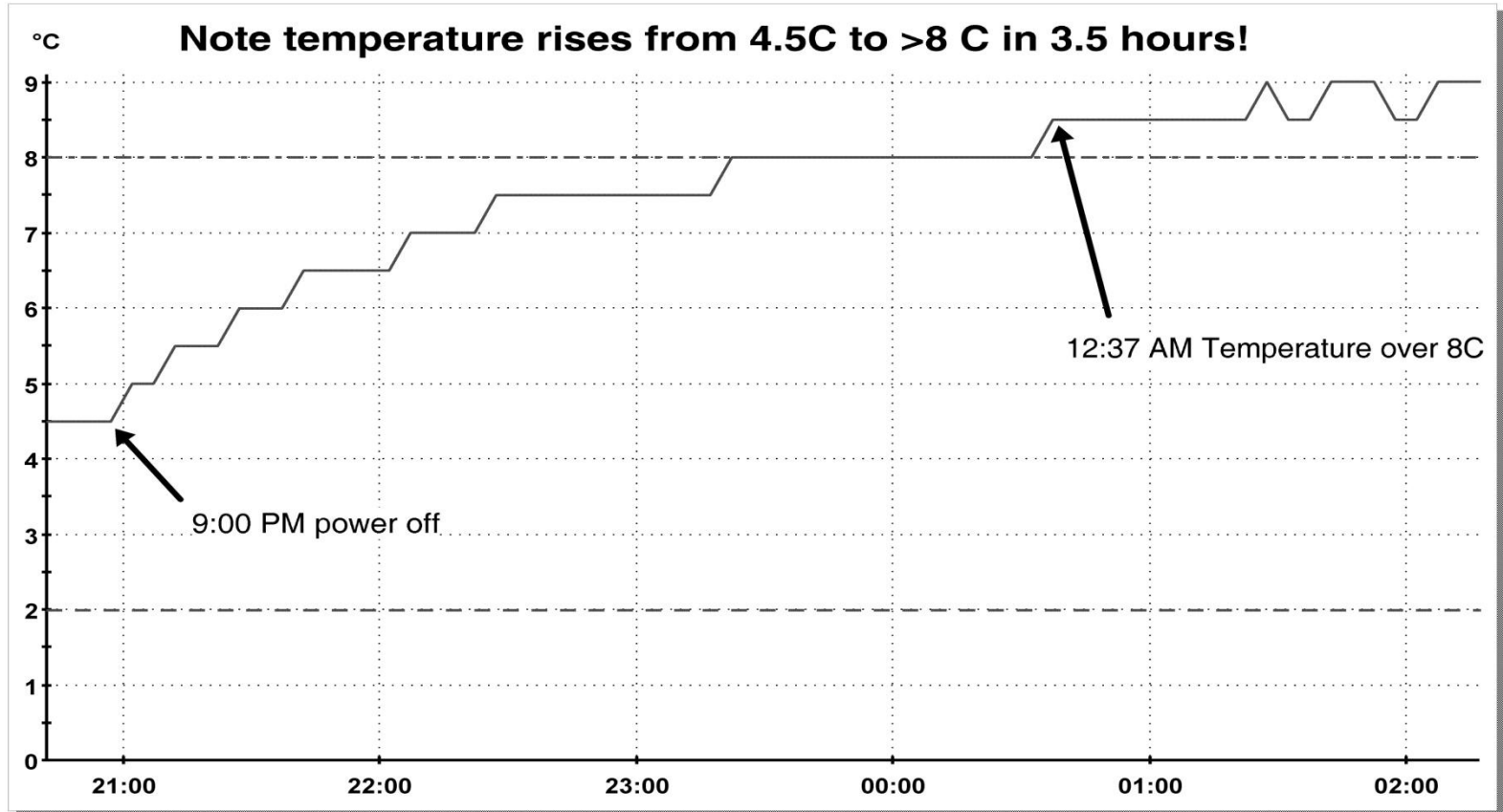
Overnight Transport using conditioned frozen water bottles in soft pack cooler.



From:- 31 January 2013 17:10:06 To:- 01 February 2013 09:50:06

# Refrigerator Power Off Test

Power Off Test on combo refrigerator with reasonable cold mass



— Celsius — High Alarm — Low Alarm

From:- 28 November 2012 20:42:11 To:- 29 November 2012 02:17:11

# Summary

- Keep a case or more of frozen water bottles in the office at all times to increase your options for transport.
- Some of the best advice I ever received in Med School – “Don’t Just DO Something, Stand There!”- Shelter In Place is a real option!
- Use frozen gel packs only for frozen vaccine; Use CFWB for refrigerated vaccine!

*“If Nothing In The Cooler Is Less Than Zero C, You Cannot Freeze Vaccine!”*